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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/614,795 | 07/09/2003 | Andrew J. Dannenberg | CRF D-2756 NB | 8535 |

23364 7590 10/17/2006

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| EXAMINER | |
|---|---|
| ROBERTS, LEZAH | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 10/614,795 | **Applicant(s)** DANNENBERG ET AL. | |
|---|---|---|---|
| | **Examiner** Lezah W. Roberts | **Art Unit** 1614 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 15 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *6-11*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached correspondence.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

| Lezah Roberts | Ardin Marschel |
|---|---|
| Patent Exmr. | SPE |
| AU 1614 | AU 1614 |

## DETAILED ACTION

**Claim Rejections - 35 USC § 112 – Written Description/New Matter**

Claims 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is maintained.

Applicant argues the claims are supported by the paragraphs:

> Passing of one or more screening tests of the first embodiment of the invention herein maximizes the opportunity of the agent passing the test, being successful for the treatment of and in the second embodiment herein. The more of the tests (a), (b), (c), (d), (e), (f) and (g) passed, the greater the likelihood of success.
>
> We turn now to the second embodiment of the invention herein which is directed at a method for treating a patient having or at risk for cancer, Alzheimer's disease or atherosclerosis, comprising administering a therapeutically effective amount of a selective inhibitor of COX-2 that meets at least one of, preferably at least two of, (a), (b), (c), (d), (e), (f) and (g).

Although Applicant points out the area of support, there appears to be lack of support for screening compounds to treat Alzheimer's, cancer or atherosclerosis. The screening methods are recited to test a candidate for the likelihood of success but not the likelihood of success for a specific disease. The diseases are mentioned for the second embodiment for a method of treating these diseases, not a method for screening an agent. Therefore the rejection is maintained.

**Claim Rejections - 35 USC § 112 – Enablement**

Claims 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained.

Applicant has summarized the asserted positions.

1) In regards to statement (1), Applicant has interpreted the Office Action to read "In vitro screening tests have no utility in respect to developing drugs for cancer treatment (relying on Gura and Johnson)". In regards to statement (2), Applicant has interpreted the Office Action to read "The claims are directed to screening for "likelihood of success" in treating disease and likelihood of success is not defined". Applicant argues empirical testing of cancer drugs on patients without lead up testing is not how drug development works and would not be allowed by the FDA. Rather there is screening *in vitro* to provide a rationale followed by animal studies, followed by human studies. The term "likelihood of success" does not need to be defined because one skilled in the art will understand what it means. One has to start somewhere in evaluating drugs for cancer treatment. The instant test would be considered as a starting point. Furthermore, literature shows that the normal progression from *in vitro* screening to animal studies to human clinical studies is what occurs in development of cancer drugs. The arguments are not persuasive.

In regards to statement (1), Applicant's interpretation is inaccurate therefore rendering the argument moot. The Office Action did not state *in vitro* screening test have no utility in developing cancer drugs. It takes the position that it is difficult to predict whether a drug will be effective for treating cancer. In regards to statement (2), not all cancers have the same mechanism of action, therefore, generally testing a candidate will not indicate whether a drug will be successful for all cancers, just cancers that have mechanisms that relate to the screening test. For instance if a cancer is related to a, b and c and the candidate meets the criteria for d, e, f and g. One could not predict the agent will work for the cancer just because it passed 4 out of the seven tests.

2) In regards to (3), Applicant has interpreted the Office Action to read, "The test recited in the claims are not sufficient for developing drugs for all cancers". Applicant argues, over thirty types of cancer and precancerous conditions to which the cancer applies are listed in the specification. This should be enough for reciting cancer generally. This argument is not persuasive.

The Applicant does provide a list but gives little support of how the screening methods used are related to the cancers listed. Each cancer listed as well as those not listed such as leukemia and bone cancer have different mechanisms of action. Leukemia is blood cancer, which has many treatment options including bone marrow transplants and is a complicated disease. Most of the cancers listed by Applicant are targeted to one organ in the body. The drugs used to treat breast cancer would probably not be beneficial for treating a more complicated cancer such as leukemia.

3) In regards to (4), Applicant has interpreted the Office Action to read, "The test of claim 6 are not enabled for likelihood of success in treating Alzheimer's disease (AD) because AD cannot be diagnosed without autopsy and because evaluation of treatment results is not possible because of variation of progression of disease from patient to patient". Applicant argues that AD is routinely diagnosed without autopsy. Tens of thousands are diagnosed as being affected with Alzheimer's each year. The argument is not persuasive.

The statement interpretation is just one example stated by the Examiner of diagnosing AD. It is acknowledged that the disease is diagnosed and treated while a patient is alive. It is also acknowledged that the progression varies in individual patients and symptoms can vary. The Office asserts that it would be difficult to determine treatment success or predict success because disease progression varies from patient to patient. It has also not been discussed by Applicant how the screening methods relate to AD.

4) In regards to (5), Applicant has interpreted the Office Action to read, "Data from animal models in development of drugs for treating Alzheimer's disease is not conclusive". Applicant argues the claims do not involve animal models but are a baseline for progressing further testing. Moreover, whether or not animal models may or may not provide conclusive data is irrelevant, since clinical testing would follow animal testing. This argument is not persuasive.

The Office understands that the screening tests are precursors for further testing and the screening method is a starting point for drug development. Its stance is it is

difficult to reasonably predict the likelihood of success of a drug candidate by the recited screening methods, particularly when the next stage of animal testing may yield inconclusive results. Applicant does not discuss how these screening tests relate to AD and uses cancer cells for the disclosed screening methods. Because AD is different from cancer, it is hard to correlate how treatment for one relates to the treatment for the other.

5) In regards to (6), Applicant has interpreted the Office Action to read, "The drugs to which the testing of the claims is directed are counter indicated for treating or preventing atherosclerosis because they pose cardiovascular risk." Applicant argues drug safety is an issue for the FDA and not the PTO. The PTO should not interfere with the current scenario. The argument is persuasive and the PTO has no intentions with interfering with the job of the FDA.

6) Applicant also argues inflammation contributes to each of the diseases mentioned in the claims and the tests of claim 6 are known to be directed to inflammatory activities. These test indicate whether a potential drug may provide anti-inflammatory benefit by route in addition to COX-2 inhibition. This argument is not persuasive.

Applicant does not indicate in the claims the agents are used to treat inflammation associated with the diseases nor does the specification appear to indicate the agents will be used for this purpose in the embodiment that the claims encompass, which is screening for "likelihood of success".

Claims 6-11 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Ardin H. Marschel 10/2/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER